Application No.: 10/630,098

Docket No. 03-001US

REMARKS

Rejections under 35 U.S.C. § 103(a)

Claims 1, 4-7, 10, 22, 23, 25, and 27-35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,092,333 to Tsuchida et al. (hercinafter "Tsuchida") in view of U.S. Patent No. 5,303,704 to Molacek et al. (hereinafter "Molacek").

Claim 24 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Tsuchida in view of Molacek in further view of Hrdlicka.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the applied reference (or references when combined) must teach or suggest all the claim limitations. See MPEP § 2143. Applicant respectfully submits that the applied references do not satisfy these criteria.

Claims 1 and 22 recite:

- a lead body having a proximal end and a distal end;
- a plurality of connectors positioned proximate the proximal end;
- a plurality of electrodes positioned proximate the distal end;
- a plurality of conductors extending through the lead body with each conductor electrically connecting at least one connector with at least one electrode; and
- a plurality of expansion sections longitudinally disposed along the lead body between the plurality of connectors and the plurality of electrodes, wherein an amount of slack for each conductor is contained with each expansion section of the plurality of expansion sections;

wherein the lead body and the conductors possess physical characteristics such that, upon application of a stretching force to the lead body, a diameter of the lead body in one or several expansion sections is reduced and the slack for each conductor in one or several expansion sections is at least partially taken up so as to allow the distance between the plurality of connectors and plurality of electrodes to be increased.

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Claim 29 recites:

- a lead body having a proximal end and a distal end;
- a plurality of electrodes positioned proximate the distal end;
- a plurality of conductors extending through the lead body with each conductor electrically connecting to at least one electrode; and
- a plurality of expansion sections longitudinally disposed along the lead body between the distal and proximal ends, wherein an amount of slack for each conductor is contained with each expansion section of the plurality of expansion sections;

wherein the lead body and the conductors possess physical characteristics such that, upon application of a stretching force to the lead body, a diameter of the lead body in one or several expansion sections is reduced and the slack for each conductor in one or several expansion sections is at least partially taken up so as to allow the distance between the plurality of electrodes and the proximal end to be increased.

In the Office Action, the rejection asserts that Tsuchida discloses "electrode 3."

Office Action, page 3. However, review of the detailed description of Tsuchida reveals that there is no electrode shown in catheter of Tsuchida. Specifically, the detailed description describes element 3 as "sensor 3" to which wires 4 and 5 connect. Col. 2, lines 65-68 of Tsuchida. Moreover, as shown in FIGURES 1-5 of Tsuchida, sensor 3 is completely enclosed within the catheter (see also claim 1 of Tsuchida) and, therefore, could not be used as an electrode.

Additionally, the Office Action asserts that the catheter of Tsuchida is "interpreted" as a lead, because it is a means to connect circuit elements. Applicant respectfully submits that there is no basis in Tsuchida to support this assertion. Also, Applicant notes that there is only one side of the catheter in Tsuchida that possess an electrical connector terminal (see connector element 6 in Fig. 1). Because there is only one electrical connector terminal, there can be no connection of multiple circuit elements using the catheter of Tsuchida.

Therefore, the catheter of Tsuchida is totally inconsistent with leads that are used to deliver electrical stimulation to patients through electrodes as claimed.

In the Office Action, the rejection under 35 U.S.C. § 103(a) relies upon Molacek to teach multiple electrodes, conductors, and connectors. The Office Action asserts that it would have been obvious to provide the multiple electrodes, conductors, and connectors of Molacek to the catheter of Tsuchida "to provide bipolar stimulation or stimulation to several areas of the body." Office Action, page 4. The catheter of Tsuchida is not disclosed as being

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related to providing stimulation to a patient in any manner. The catheter of Tsuchida is only described as including a single sensor. Accordingly, the proffered motivation is only based upon an attempt to reconstruct the claimed subject matter from various parts shown in divergent references by using the claimed subject matter as a guide to assemble such parts. However, it is well settled that such a motivation is inadequate as a matter of law.

Hrdlicka is merely relied upon in the Office Action to show an RF-powered pulse generator. Hrdlicka does not provide valid motivation for transforming the catheter of Tsuchida into a stimulation lead having a plurality of electrodes, conductors, and connectors as proposed in the Office Action.

Therefore, the applied references (either alone or in combination) do not provide the requisite motivation to arrive at the subject matter of claims 1, 22, and 29. A prima facie case of obviousness has not been established for these claims. All other claims are likewise patentable due to their dependency from claims 1, 22, and 29 in addition to the novel and nonobvious limitations explicitly recited in the dependent claims.

Conclusion

Applicant respectfully submits that the application is in condition for allowance and requests the Examiner to pass the application to issue.

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Respectfully submitted,

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